

REMARKS

Claims 29, 42, 45, 48, 54, 58-67, 89-90, and 92-105 are pending and stand rejected. Claims 45, 48, 92, and 93 have been canceled. Claims 29, 42, 58-67, 89, and 95-104 have been amended. The specification has been amended to properly designate the use of trademarks. No new matter has been introduced. Reconsideration and allowance of Claims 29, 42, 54, 58-67, 89, 90, and 94-105 is respectfully requested in view of the following remarks.

The Objection to the Specification

The Specification has been amended at paragraphs [00110], [00142], [00187], [00190], [00197], [00206], [00209], and [00220] to properly designate the use of trademarks. No new matter has been introduced.

The Rejection of Claims 29, 42, 45, 48, 54, 58-67, 89-90, and 92-105 Under 35 U.S.C. § 112,

First Paragraph (Enablement)

Claims 29, 42, 45, 48, 54, 58-67, 89-90, and 92-105 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner acknowledges that the specification is enabling for assigning a human breast cancer patient to one of a plurality of categories based on the status of prognosis using the specific markers as listed in Tables 1-5 of the specification. However, the Examiner has taken the position that the specification does not reasonably provide enablement for assigning a non-human breast cancer patient based on the status of prognosis and predicting the prognosis of a non-human breast cancer patient.

While not acquiescing to the Examiner's position, but in order to facilitate prosecution, independent Claims 29, 42, and 89, have been amended as follows. Claim 29 has been amended to replace the term "individual" with the term "human individual." Claims 42 and 89 have been

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amended to replace the term "breast cancer patient" with the term "human breast cancer patient." Support for these amendments is found in the specification as filed; for example, at page 18, paragraph [0063]; page 90, paragraph [00222], to page 99, paragraph [00261]; and TABLES 1–5.

Accordingly, removal of this ground of rejection is respectfully requested.

The Rejection of Claims 29, 42, 45, 48, 54, 58–67, 89–90, and 92–105 Under 35 U.S.C. § 112, Second Paragraph (Indefiniteness)

Claims 29, 42, 45, 48, 54, 58–67, 89–90, and 92–105 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention.

The Examiner notes that Claims 29 (steps a and b), 42 (steps a and b), 58–67, 89 (classifying step), and 95–104, recite commas which lack clarity because it is unclear if these commas are intended to mean "and," "or," or "and/or." In order to clarify the invention, Claims 29, 42, 58–67, 89, and 95–104 have been amended as follows.

Claims 29, 42, 60, 61, 89, 97, and 98 have been amended to replace the phrase "ER⁻, BRCA1" with the phrase "ER⁻ and BRCA1."

Claims 29, 42, 58, 59, 89, 95, and 96 have been amended to replace the phrase "ER⁻, sporadic", with the phrase "ER⁻ and sporadic."

Claims 29, 42, 62, 63, 89, 99, and 100 have been amended to replace the phrase "ER⁺, ER/AGE high" with the phrase "ER⁺ and ER/AGE high."

Claims 29, 42, 64, 65, 89, 101, and 102 have been amended to replace the phrase "ER⁺, ER/AGE low, LN+" with the phrase "ER⁺, ER/AGE low and LN+."

Claims 29, 42, 66, 67, 89, 103, and 104 have been amended to replace the phrase "ER+, ER/AGE low, LN⁻" with the phrase "ER+, ER/AGE low and LN⁻."

The Examiner has also taken the view that Claim 29 (lines 33, 36), Claim 42 (lines 18, 21), and Claim 89 (lines 19, 22) recite the term "representative of," which the Examiner characterizes as vague and indefinite. While not acquiescing to the Examiner's position, but in order to facilitate prosecution, Claims 29, 42, and 89 have been amended as follows.

Claim 29 has been amended to replace the phrase,

wherein said good prognosis template comprises measurements of the levels of expression of said at least two respective genes that are representative of levels of expression of said at least two respective genes in a plurality of good outcome patients, and said poor prognosis template comprises measurements of the levels of expression of said at least two respective genes that are representative of levels of expression of said at least two respective genes in a plurality of poor outcome patients,

with the phrase, "wherein said good prognosis template comprises measurements of the average levels of expression of said at least two respective genes in a plurality of good outcome patients, and said poor prognosis template comprises measurements of the average levels of expression of said at least two respective genes in a plurality of poor outcome patients." Basis for these amendments is present in Claims 48 and 93, now canceled.

Similarly, Claims 42 and 89 have been amended to replace the phrase,

wherein said good prognosis template comprises measurements of levels of transcripts of, or proteins encoded by, said respective genes in said plurality of genes that are representative of levels of transcripts of, or proteins encoded by, said respective genes in a plurality of good outcome

patients, and said poor prognosis template comprises measurements of levels of transcripts of, or proteins encoded by, said respective genes in said plurality of genes that are representative of levels of transcripts of, or proteins encoded by, said respective genes in a plurality of poor outcome patients,

with the phrase, "wherein said good prognosis template comprises measurements of average levels of transcripts of, or proteins encoded by, said respective genes in a plurality of good outcome patients, and said poor prognosis template comprises measurements of average levels of transcripts of, or proteins encoded by, said respective genes in a plurality of poor outcome patients." Basis for these amendments is present in Claims 48 and 93, now canceled.

Accordingly, removal of this ground of rejection is respectfully requested.

The Rejection of Claims 29, 42, 45, 48, 58, 60, 89, 90, 92, 93, 95, 97, and 105 Under 35 U.S.C. § 102(e) as Being Anticipated by U.S. Patent Appl. Publication No. 2004/0058340 (Dai et al.)

Claims 29, 42, 45, 48, 58, 60, 89, 90, 92, 93, 95, 97, and 105 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2004/0058340 (Dai et al.). Applicants respectfully traverse this ground of rejection for at least the following reasons.

Claims 45, 48, 92 and 93 have been canceled. Independent Claims 29, 42, and 89 (from which Claims 58, 60, 90, 95, 97, and 105 depend) have been amended as described *supra*. Dai et al. does not teach or suggest the methods of Claim 29, 42 and 89, as amended. Dai et al. describes a set of marker genes that can be used for classifying a sample as ER+ versus ER-; a set of marker genes that can be used for classifying a sample as BRCA+ versus sporadic; and a set of marker genes that can be used for classifying a sample as having a good versus a poor

prognosis. However, in contrast to the claimed invention, Dai et al. does not describe a method for assigning an individual to one category in a clinical trial if said individual is classified as having a good prognosis, and assigning said individual to a second category in said clinical trial if said individual is classified as having a poor prognosis, wherein said good or poor prognosis is determined by different sets of marker genes depending on whether the patient is ER⁻ and sporadic; ER⁻ and BRCA1; ER⁺ and ER/AGE high; ER⁺, ER/AGE low and LN⁺; or ER⁺, ER/AGE low and LN⁻.

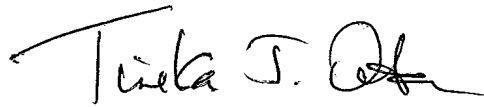
Moreover, nothing in Dai et al discloses or suggests to use a comprehensive prognosis based on (1) classifying an individual as ER⁻ and BRCA1; ER⁻ and sporadic; ER⁺ and ER/AGE high; ER⁺, ER/AGE low and LN⁺; or ER⁺, ER/AGE low and LN⁻; followed by (2) determining good or poor prognosis for said individual using a set of marker genes that depends on the classification of the individual. As is clear from Table 7 entitled "Average error rate for the patient subset approach compared with the previously-described 70 gene classifier" on page 98 of the present application, the comprehensive prognosis according to the claimed invention significantly improves the prediction error rate when compared with the 70 gene classifier that was used for prognosticating a sample in Dai et al. See instant application at page 98, paragraph [00259]. Therefore, withdrawal of the rejection pursuant to 35 U.S.C. § 102 based on Dai et al. is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, it is believed that all the pending claims are in condition for allowance. Reconsideration and favorable action are requested. If any issues remain that may be expeditiously addressed in a telephone interview, the Examiner is encouraged to telephone applicants' attorney at the number set forth below.

Respectfully submitted,

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